



CERTIFICATE

This is to certify that the company

Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1
79331 Teningen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design, manufacturing, repair and distribution of electrosurgical devices, accessories and surgical instruments, supplied in sterile and non-sterile condition.

-AUS (a), CND, JPN, BRA, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

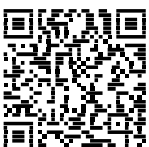
Certificate registration no.	003171 MDSAP16
Certificate unique ID	170782633
Effective date	2024-03-29
Expiry date	2027-03-28
Frankfurt am Main	2024-03-17



DQS Medizinprodukte GmbH

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Product Manager



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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.

The validity of this certificate can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 003171 MDSAP16
Certificate unique ID: 170782633
Effective date: 2024-03-29

Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1
79331 Teningen
Germany

Audited site

003171
Günter Bissinger Medizintechnik GmbH
Hans-Theisen-Str. 1
79331 Teningen/Baden
Germany

REPs FEI No.: site scope and country-specific requirements

Design, manufacturing, repair and distribution of
electrosurgical devices, accessories and surgical
instruments, supplied in sterile and non-sterile
condition.

-AUS (a), CND, JPN, BRA USA (a,b,c,d)
REPs FEI No.: F004973



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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821